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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,986	02/25/2005	Tadashi Nakajima	05116/HG	5004

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EXAMINER	
BASQUILL, SEAN M	

ART UNIT	PAPER NUMBER
1612	

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01/12/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/525,986	NAKAJIMA ET AL.	
	Examiner	Art Unit	
	Sean Basquill	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 13-22* is/are pending in the application.

4a) Of the above claim(s) *5-8 and 17-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 13-16, 21, 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5 Dec 2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Previous Rejections

1. Applicants' arguments, filed 29 October 2008, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Specification

2. The disclosure remains objected to because of the following informalities: while the amendments made to the brief descriptions of the drawings have clarified and removed the examiners objections as to the description of Figures 1 and 2, the Compounds A and B as referred to in the description of Figures 3 and 4 remains unclear. Applicant is requested to either incorporate the specific compound names into the brief descriptions of Figures 3 and 4, or otherwise indicate that the Compounds A and B referred to therein are the same Compounds A and B as referred to in Figures 1 and 2, respectively.

Appropriate correction is required.

Election/Restrictions

3. Newly submitted Claim 22 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claim 22 is directed to a method of treatment dependent on withdrawn Claim 5, also directed to a method of treatment. In the

response to restriction requirement filed by applicants on May 30, 2008, the applicants elected to prosecute the pharmaceutical composition of the instant application.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, Claim 22 has been withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-4, 13-16 and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, applicant's inclusion of the phrase "consisting essentially of" only rho kinase inhibitors and prostaglandins constitutes new matter because the specification never specifically discloses the phrase, and never contemplated the exclusion of particular ingredients as implied therein.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1-4 and 13-16 stand rejected under 35 U.S.C. 103(a) as being unpatentable over EP/0286903A1 ("Bito"), in view of U.S. Patent 7,015,210 ("Aiken"), P. Vasantha Rao, et al, *Modulation of Aqueous Humor Outflow Facility by the Rho Kinase-Specific Inhibitor Y-27632*, 42 INV. OPHTHALMOL. VIS. SCI. 1029 (April 2001) ("Rao"), and U.S. Patent 6,271,224 ("Kapin") (all of record).

The rationale for this rejection is provided in the office action dated 07/29/08, the text of which is incorporated by reference herein. The examiner additionally notes that absent a clear indication in the specification or claims of what the basic and novel characteristics of the claimed composition actually are, the phrase "consisting essentially of" is construed as being equivalent in meaning to the term "comprising." *PPG v. Guardian*, 156 F.3d 1351, 1354 (Fed. Cir. 1998).

Turning now to the applicant's arguments, the examiner disagrees with the applicant's assertion that Bito requires the combination of prostaglandin and adrenergic blocking agent to effect a treatment for glaucoma. While Bito certainly presents as a preferred embodiment of their invention glaucoma treatment with a combination of prostaglandin and adrenergic blocking agent, the disclosure of Bito is not so limited. Bito clearly discloses that prostaglandins are responsible for reduction of intraocular pressure by effecting an increase in uveoscleral outflow. (C.1, L.48-50). Prior art is relevant for all it contains, and is not limited to simply the invention or preferred embodiments therein described. MPEP § 2123. By indicating that prosaglandins alone are capable of reducing intraocular pressure, for purposes of examination of the instant claims it is immaterial what additional agents are included in the preferred embodiments of Bito.

The examiner similarly disagrees with the applicant's characterization of the disclosure of Aiken. To be sure, a preferred embodiment of Aiken certainly discloses treatment of glaucoma using a combination of epoxysteroidal aldosterone receptor antagonists and prostaglandins such as latanoprost, unoprostone isopropyl, or travaprost. Regardless of the described preferred embodiments, Aiken nevertheless describes the widespread use of such prostaglandins in the reduction of intraocular pressure in treating patients with Glaucoma. (C.10, L.42-56). Within this disclosure, Aiken makes no mention of the requirement asserted by applicants that the action of prostaglandins in glaucoma treatment is tied to their administration in combination with epoxysteroidal aldosterone receptor antagonists.

Rao and Kapin clearly demonstrate that specific species of compounds of the instant invention are known to lower intraocular pressure in the treatment of glaucoma.

The art as cited by the examiner therefore discloses all elements of the instant claims, and provides explicit motivation for employing combination therapy for the treatment of glaucoma. Nevertheless, in addition to the motivation explicitly present in the above cited art, the examiner directs applicants to MPEP § 2144.06, which indicates that it is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. Where here, the claimed invention simply combines two compounds known to effectively lower intraocular pressure to form a third composition for the reduction of intraocular pressure, the combination is *prima facie* obvious regardless of any motivation to combine explicitly provided by the art.

6. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over EP/0286903A1 ("Bito"), in view of U.S. Patent 7,015,210 ("Aiken"), P. Vasantha Rao, et al, *Modulation of Aqueous Humor Outflow Facility by the Rho Kinase-Specific Inhibitor Y-27632*, 42 INV. OPHTHALMOL. VIS. SCI. 1029 (April 2001) ("Rao"), and U.S. Patent 6,271,224 ("Kapin") (all of record).

Bito, Aiken, and Rao describe different methods of treating glaucoma using prostaglandins and rho-kinase inhibitors as described above.

Kapin indicates isoquinoline compounds, preferably 1-(5-isoquinolinesulfonyl)-homopiperazine as well as pharmaceutically acceptable salts thereof, are effective in lowering IOP. (C.2, L.31-33; C.3, L.19-24). A preferred embodiment of the invention of Kapin uses the hydrochloride salt of 1-(5-isoquinolinesulfonyl)-homopiperazine, commonly known as FASUDIL.

It would have been prima facie obvious to one of ordinary skill in the art to combine the prostaglandins of Bito and Aiken with the rho-kinase inhibitors of Rao and Kapin to yield a composition for the treatment of glaucoma combining latanoprost and 1-(5-isoquinolinesulfonyl)-homopiperazine. One having ordinary skill in the art would have been motivated to combine latanoprost and 1-(5-isoquinolinesulfonyl)-homopiperazine to treat glaucoma both because of the preference for combination therapy expressed by Bito and Aiken and also because both latanoprost and 1-(5-isoquinolinesulfonyl)-homopiperazine are known independently to lower intraocular pressure in the treatment of glaucoma. It is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for

the same purpose, in order to form a third composition to be used for the very same purpose. MPEP § 2144.06.

Conclusion

No Claims are allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean Basquill whose telephone number is (571) 270-5862. The examiner can normally be reached on Monday through Thursday, between 8AM and 6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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